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IN THE UNITED STATES DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA

IN RE: ZIMMER DUROM HIP CUP PRODUCTS LIABILITY LITIGATION This applies to: WENDY HUSTON, Plaintiff, vs. ZIMMER BIOMET, BIOMET, INC., ZIMMER, INC., ZIMMER BIOMET HOLDINGS, INC., Defendants.	CASE NO.: MDL: 2158 COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. Plaintiff, WENDY HUSTON, states and brings this civil action before the Court for the United States District Court for the Central District of California as a related action in the matter entitled IN RE: ZIMMER DUROM HIP CUP PRODUCTS LIABILITY LITIGATION, MDL No. 2158.

2. This action is brought pursuant to 20 USC § 1332, as diversity of citizenship exists between the parties.

3. Venue is proper under 28 USC § 1391 as defendants named herein do business within this district.

4. Plaintiff, WENDY HUSTON, is a resident of the state of California and claims damages as set forth below.

5. Plaintiff was born on 06/13/1951.

ALLEGATIONS AS TO DEVICE(S) AND INJURIES

6. Plaintiff was implanted with a Zimmer Durom Hip Cup Device on her left hip on or about 12/07/2006 at Hoag Hospital by Dr. Stephen Mikulak.

7. Plaintiff was implanted with a Zimmer Durom Hip Cup Device on her right hip on or about 05/07/2007 at Hoag Hospital by Dr. Stephen Mikulak.

8. Plaintiff suffered personal and economic injuries as a result of the implantation of the following Zimmer Durom Cup(s) Device(s):
Left hip: Metasul® Durom® Acetabular Component uncemented 50/44 Code J, Ref. 01.00214.150, Lot 2337803; Metasul® LDH ™ Head 44 Code J Taper 18/20.
Right hip: Metasul® Durom® Acetabular Component uncemented 48/42 Code H, Ref. 01.00214.148, Lot 2357531; Metasul® LDH ™ Head 42 Code H Taper 18/20 which had been implanted on the above dates. Subsequent to November 2, 2013, plaintiff was advised that blood tests showed that she had elevated levels of Cobalt and Chromium in her blood, which elevated levels were caused by the above-referenced hip replacement components, which were manufactured with Cobalt and Chromium. Subsequent thereto, on or about December 20, 2013, plaintiff was advised that x-rays showed that the cup components were loose. Following this, additional blood tests were performed on or about January 17, 2014, that confirmed that plaintiff had elevated levels of Cobalt and Chronium.

9. Plaintiff underwent bilateral hip revision surgeries with respect to the defective Zimmer Durom Cup(s) Devices on 02/25/2014 at Hoag Orthopedic Institute by Dr. Stephen Mikulak.

10. Plaintiff has suffered injuries as a result of implantation and revision/explantation of the Zimmer Durom Cup Devices manufactured by defendants.

11. The defendants by their actions or inactions, proximately caused Plaintiff's injuries.

12. Plaintiff claims damages as a direct and proximate result of defendant's wrongful conduct, plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages.

13. Neither plaintiff nor her physicians, through the exercise of reasonable diligence, could have detected the defective nature of the Zimmer Durom Cup Device (hereinafter "Defective Device") any earlier than the evidence of loosening and/or other indication for planned revision of the defective device(s).

14. As a result of the injuries plaintiff sustained, she is entitled to recover economic compensatory damages for pain and suffering and emotional distress and for economic loss as well as punitive damages.

15. Plaintiff's left hip Zimmer Durom Cup Device bears catalog number Z-2418-2008, lot number 2337803, REF 01.00214.150.

16. Plaintiff's right hip Zimmer Durom Cup Device bears catalog number Z-2417-2008, lot number 2357531, REF 01.00214.148.

COUNT I - STRICT LIABILITY FAILURE TO WARN AND INSTRUCT

17. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

18. At all relevant times hereto, defendants were engaged in the development, testing, manufacturing, marketing and sales of the Defective Device. Defendants designed, manufactured, assembled and sold the Defective Device to medical professionals and patients knowing that they would then be implanted in patients in need of hip prosthesis.

19. Defendants distributed and sold the Defective Device in the condition in which it left its place of manufacture in its original form of manufacture which included the defects described herein. The Defective Device was expected to and

did reach plaintiff without substantial change or adjustment in its condition as manufactured and sold by defendants.

20. The Defective Device designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the Defective Device. Plaintiff was and is in a class of persons that defendants should have considered to be subject to the harm caused by the defective nature of the Defective Device.

21. The Defective Device was implanted and used in the manner for which it was intended. This use has resulted in severe physical and emotional and other injuries to plaintiff.

22. Defendants knew or should have known through testing, adverse event reporting or otherwise that the Defective Device created a high risk of bodily injury and serious harm.

23. As a direct and proximate result of defendant's wrongful conduct, plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result, plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff is entitled to compensatory damages in an amount to be proven at trial.

COUNT II - STRICT LIABILITY - DESIGN DEFECT

24. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

25. Defendants are the manufacturer and/or supplier of the Defective Device and placed this device into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and or formulation of the Defective Device.

26. The Defective Device manufactured, marketed, distributed and/or

supplied by defendants was defective in design or formulation in that when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

27. The Defective Device was expected to and did reach plaintiff without substantial change in condition. Alternatively, the Defective Device manufactured and/or supplied by defendants was defective in design or formulation because when the Defective Device left the hands of defendants, the manufacturers and/or suppliers, the Defective Device was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

28. The Defective Device was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 et seq. and the Medical Devices Amendment thereto (hereinafter 'FDCA"). The facilities or controls used by defendants in the manufacture, packing, storage, or installation of the Defective Device were not in conformity with applicable requirements of the FDCA.

29. The Defective Device manufactured and/or supplied by defendants was defective due to inadequate warnings and/or inadequate trials, testing and studies, inadequate exposure of the real risks inherent with the device as determined by the clinical trials and inadequate reporting of the results of the clinical trials and post-marketing clinical experiences with the device.

30. The Defective Device manufactured and/or supplied by defendants was defective due to inadequate post-marketing warnings or instructions because after defendants knew or had reason to know of the risk of injury from the Defective Device, it failed to provide adequate warnings to the medical community, patients, and the public including plaintiff, and continued to promote and advertise the Defective Device as safe and effective.

31. The Defective Device was designed, manufactured, distributed, tested, sold, marketed, and advertised defectively by defendants. As a direct and

proximate cause of defendants' defective design of the Defective Device, plaintiff and other patients had the device implanted in their bodies and suffered, and will continue to suffer increased risk of long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery, and pain and suffering.

32. Defendants were or should have been in possession of evidence demonstrating that the Defective Device caused serious injuries and would fail. Nevertheless, defendants continued to market the device by providing false and misleading information with regard to the safety and efficacy of the Defective Device.

33. Defendants' actions as described above were performed willfully, intentionally and with reckless disregard for the rights of plaintiff, other patients and the public.

34. As a result of defendants' conduct, plaintiff suffered the losses, injuries and damages as specified herein.

COUNT III - STRICT LIABILITY - MANUFACTURING DEFECT

35. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

36. At all times material hereto, defendants engaged in the business of developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, retailing, supplying and/or selling the defective product sold under the name "Durom System" and through that conduct have placed the Defective Device into the stream of commerce in the State of California. On information and belief, the Defective Device was defective at the time of its manufacture and marketing.

37. The Durom System was defectively manufactured because the foreseeable risks of mechanical malfunction and failure outweighed the benefits associated with the Durom System so as to be unreasonably dangerous to

consumers, including plaintiff.

38. The Durom System was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act U.S.C. §321 et seq. and the Medical Devices Amendment thereto (hereinafter "FDCA"). The facilities or controls used by defendants in the manufacture, packing, storage or installation of the Durom System were not in conformity with applicable requirements of the FDCA.

39. Defendants expected the Defective Device to reach, and it did in fact reach, consumers in the State of California, including plaintiff without substantial change or adjustment to its mechanical function.

40. The Durom System was intended for use in hip replacement procedures for consumers and plaintiff became a consumer and relied upon the safety of the manufacturing defendants' product.

41. Defendants failed to warn the public, including plaintiff, of the risk of suffering the type and manner of injuries suffered by plaintiff, which risks and/or dangers were known or should have been known to defendants.

42. Defendants did in fact develop, test, assemble, manufacture, package, label, prepare, distribute, market, retail, supply and/or sell the Defective Device including the distribution of promotional materials, publicity and/or information to plaintiff, including but not limited to the information printed on the instructions for use, labeling and/or packaging.

43. At all times relevant herein, the Defective Device (and the sales and promotional materials) developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, retailed, supplied, and/or sold by defendants was defective, including on or more of the following particulars:

(a) The Durom System contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting plaintiff to risks which exceeded the benefits of the device;

(b) The Durom System was defective in design and formulation making use of the product more dangerous than the ordinary consumer would expect;

(c) The Durom System contained insufficient and/or incorrect warnings to alert consumers and users, including plaintiff, of adverse effects and risks thereto;

(d) The Durom System was not safe for its intended use;

(e) The Durom System was inadequately tested; and/or

(f) The Durom System was not accompanied by adequate instructions and/or wrings to fully apprize the implanting and/or prescribing physicians as well as the ultimate consumers, including plaintiff, of the full nature or extent of the risks and side effects associated with its use.

44. Defendants knew and intended that the Defective Device would be purchased from defendants by members of the general public and would be used by such purchasers without any inspection for defects, and would rely upon the representations made by defendants on the product label, in other promotional and sales materials and otherwise.

45. At the time of its manufacture and sale to plaintiff, the Defective Device was unsafe and defective to consumers using said product for its advertised purposes and in a reasonably foreseeable manner, in that it posed an unreasonably high risk of serious injury to consumers, which information was concealed by defendants.

46. Prior to the manufacturing, sale and distribution of the Defective Device, defendants knew, or was reckless in not knowing, that said Defective Device was in a defective condition and that those who were implanted with said device were at an unreasonable risk of experiencing injury. Further, defendants through their officers, directors and managing agents, had notice and knowledge from several sources prior to the date of the marketing and sale of said Defective Device to plaintiff that the product presented potentially a substantial and unreasonable risk of harm to the consumer, including plaintiff, and as such said

consumers were unreasonably subjected to risk of injury from the use of that product.

47. Despite such knowledge, defendants through their officers, directors and managing agents, knowingly and deliberately failed to remedy the known defects in the Defective Device and failed to warn the public, including plaintiff, of the serious risk of injury occasioned by the defects inherent in the product.

48. Upon information and belief such failure to notify the public, including plaintiff, was for the purpose of increasing sales and enhancing their profits and defendants intentionally proceeded with the manufacturing, sale and marketing of the Defective Device knowing that persons would be exposed to serious potential danger in order to advance their own pecuniary interests.

49. Plaintiff used the medical device for its intended purpose.

50. Plaintiff could not have discovered any defect in the Defective Device or accompanying sales and promotional materials through the exercise of due care.

51. Defendants as manufacturer, marketer, retailer, distributor and seller of the Defective Device and like products are held to the level of knowledge of an expert in its field.

52. Plaintiff did not have substantially the same knowledge as an adequate warning from defendants should have communicated.

53. As a direct and proximate result of the defective and unreasonably dangerous condition of the Defective Device, as aforesaid, plaintiff sustained the injuries and damages as herein alleged.

COUNT IV - NEGLIGENCE

54. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

55. Defendants were under a duty to use reasonable care in the design, manufacture, the provision of warnings accompanying the Defective Device, retail, distribution and sale of the Defective Device.

56. Manufacturing defendants were under a duty to use reasonable care to design and manufacture the Durom System so that it would be reasonably safe for their intended use.

57. Defendants breached this duty by among other things:

(a) Failing to exercise due care in designing, developing, manufacturing, retailing, distributing and selling the Defective Device so as to avoid the aforementioned risks to individuals using these products;

(b) Failing to include adequate warnings with the Defective Device that would alert plaintiff and other consumers to its potential risks and serious side effects;

(c) Failing to adequately and properly test the Defective Device before placing these products on the market;

(d) Failing to conduct sufficient testing on the Defective Device which if properly performed would have shown that the product had serious side effects, including but not limited to, loosening and causing pain and discomfort in the hip;

(e) Failing to adequately warn plaintiff that use of the Defective Device carried a risk of serious side effects, including but not limited to, loosening, pain and discomfort and disability;

(f) Failing to provide adequate post-marketing warnings or instructions after defendants knew, or should have known, of the significant risks of injuries and events from the use of the Defective Device; and

(g) Placing an unsafe product into the stream of commerce.

58. As a direct and proximate result of defendants' negligence, plaintiff sustained the injuries and damages as herein alleged.

COUNT V - NEGLIGENCE *PER SE*

59. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

60. Defendants have an obligation to not violate the law in the manufacture,

design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device and otherwise distributing the Defective Device.

61. Defendants' acts and omissions constitute an adulteration, misbranding or both as defined by the Federal Food, Drug and Cosmetic Act U.S.C. §§331(a) and 333(a)(2) and the California Food, Drug and Cosmetic Law (Sherman Law) Health & Safety Code 109875 et seq., and constitute a breach of duty subjecting defendants to civil liability for all damages arising therefrom under theories of negligence *per se*.

62. Plaintiff as a purchaser of the Defective Device is within the class of persons the statutes and regulations (described above are designed to protect and plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

63. As a direct and proximate result of defendants' wrongful conduct, plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VI - BREACH OF EXPRESS AND IMPLIED WARRANTIES

64. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

65. At the time and place of the sale, distribution and supply of the Defective Device product to plaintiff, defendants expressly represented and warranted the Defective Device was safe and impliedly warranted that the product was reasonably fit for its intended purpose and was of marketable quality.

66. In fact, however, the Defective Device was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said product and accordingly defendants breached these warranties.

67. As a direct and proximate result of defendants' breach of warranty, plaintiff has sustained the injuries and damages as herein alleged.

COUNT VII - NEGLIGENT MISREPRESENTATION

68. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

69. At the time defendants manufactured, designed, marketed, sold and distributed the Defective Device for use by plaintiff, defendants knew or should have known of the use for which the Defective Device was intended and the serious risks and dangers associated with such of the Defective Device.

70. Defendants owed a duty to physicians and patients using the Defective Device, including plaintiff, to accurately and truthfully disclose the risks of the Defective Device. Defendants breached that duty by misrepresenting and/or failing to adequately warn plaintiff's physicians, the medical community, plaintiff, and the public about the risks of the Defective Device, which defendants knew or in the exercise of diligence should have known.

71. As a direct and proximate result of defendants' wrongful conduct, plaintiff sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT 8 - INTENTIONAL MISREPRESENTATION

72. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

73. Defendants having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the Defective Device, owed a duty to provide accurate and complete information to plaintiff, her physicians, and the public regarding the Defective Device.

74. However, defendants misled plaintiff, her physicians, and the public into believing that the Defective Device was safe and effective for use in hip

replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince physicians and patients to use the Defective Device even though defendants knew or should have known that the Defective Device was unreasonably unsafe. Defendants also failed to warn physicians and the pubic about the safety risks of the Defective Device and the Durom System they designed, marketed and sold.

75. Defendants' advertising program and promotional items by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Defective Device was safe for human use, had no unacceptable side effects and would not interfere with daily life.

76. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Defective Device. Defendants through promotional practices as well as the publication of medical literature, deceived potential treating physicians, plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including plaintiff regarding the safety of the Defective Device.

77. Defendants expressly denied that the Defective Device created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Defective Device.

78. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, physicians, plaintiff, and the public, the truth regarding the Defective Device failures for months if not years, all the while undertaking a major advertising campaign to sell the Defective Device. Defendants received reports of the Defective Device from various sources and intentionally withheld this information from physicians and patients, while continuing to sell the Defective Device for implantation in individuals such as

plaintiff.

79. Further, even as defendants eventually may have disclosed some information regarding the Defective Device defects, any such disclosures were incomplete and misleading.

80. Defendants effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the Defective Device. The truth did not begin to emerge until at the earliest May 2008 when defendant issued a letter to physicians that suggested that Defective Device defects were arising because of doctors' surgical techniques. This letter was inadequate and failed to fully inform physicians, patients, including plaintiff and the public of the true defects in the Defective Device, defects that were known to defendants. Even after the letter, defendants' sales representatives continued to assure physicians and patients that the Defective Device was adequate and reliable for the purpose intended and they continued to sell the Defective Device.

81. Through the materials they disseminated, defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the Defective Device.

82. Defendants possessed evidence demonstrating the Defective Device was defective and likely to fail and injure patients. Nevertheless, defendants continued to market the Defective Device by providing false and misleading information with regard to its safety to plaintiff and plaintiff's physicians.

83. Defendants engaged in all the acts and omissions described above with the intent that plaintiff's physicians and plaintiff would rely on these misrepresentations, deception and concealment in deciding to use defendants' Defective Device rather than another ZIMMER product or a competitor's similar product.

84. Plaintiff and plaintiff's physicians justifiably relied to their detriment on defendants' intentional and fraudulent misrepresentations as set out above.

This reliance proximately caused the injuries and damages described in this complaint.

85. As a direct and proximate result of defendants' wrongful conduct, plaintiff sustained and will continue to sustain severe physical injuries. Plaintiff suffered and will continue to suffer severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages and in an amount to be proven at trial.

COUNT IX - CONSTRUCTIVE FRAUD

86. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

87. At the time defendants sold the Defective Device to plaintiff, defendants were in a unique position of knowledge concerning the safety and effectiveness of the Defective Device which knowledge was not possessed by plaintiff or her physicians and defendants thereby held a position of superiority over plaintiff.

88. Through their unique knowledge and expertise regarding the defective nature of the Defective Device and through their statements to physicians and their patients in advertisements, promotional materials and other communications, defendants professed to plaintiff that they had knowledge of the truth of the representation that the Defective Device was safe and effective for its intended use and was not defective.

89. Defendants' representations to plaintiff, the medical community and the public were unqualified statements made to induce plaintiff and her physicians to purchase and use the Defective Device; and plaintiff and her physicians relied upon the statements prior to purchasing the device and having it implanted in plaintiff's body.

90. Defendants took unconscionable advantage of their dominant position of knowledge with regard to plaintiff and her physicians and engaged in

constructive fraud in their relationship with plaintiff. Plaintiff and her physicians reasonably relied on defendants' representations.

91. As a foreseeable, direct and proximate result of defendants' willful and wrongful conduct and reckless disregard for plaintiff's well-being, plaintiff sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory, punitive and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT X - UNJUST ENRICHMENT

92. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

93. As the intended and expected result of their conscious wrongdoing, defendants have profited and benefitted from the purchase of defendants' Defective Device by plaintiff.

94. Defendants have voluntarily accepted and retained these profits and benefits, derived from plaintiff, with full knowledge and awareness that as a result of defendants' fraud and other conscious and intentional wrongdoing, plaintiff was not receiving a product of the quality, nature or fitness that had been represented by defendants or that plaintiff, as a reasonable consumer, expected.

95. By virtue of the conscious wrongdoing alleged above, defendants have been unjustly enriched at the expense of plaintiff, who are entitled to in equity and hereby seek, the disgorgement and restitution of defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the defendants' unjust enrichment.

COUNT XI - PUNITIVE DAMAGES

96. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

97. The acts of defendants were willful and wanton, malicious and showed a total disregard for human lift and human suffering. Based upon the acts alleged herein, defendants knew or should have known in light of the surrounding circumstances that their conduct would naturally and probably result in injury and damage. Defendants continued such conduct with malice and/or reckless disregard of the consequences from which malice may be inferred. Plaintiff should be awarded punitive damages against defendants based upon the acts herein so as to punish defendants and deter similar conduct.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment against defendants as follows:

1. For compensatory damages requested and according to proof;
2. For punitive or exemplary damages against defendants;
3. For all applicable statutory damages of the state whose laws govern this action;
4. For an award of attorney's fees and costs;
5. For prejudgment interest and the costs of suit; and
6. For such other and further relief as this Court may deem proper and just;

JURY DEMAND

Plaintiff hereby demands trial by jury as to all claims in this action.

Respectfully submitted,

DATED: October 6, 2015 LAW OFFICES OF DAVID P. CRANDALL

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